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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Jeffrey E. FETTERMAN, et al.

Application No.: 10/722,262

Confirmation No : Group Art Unit:

Filed: November 25, 2003

Examiner: Rajiv J. Raj

Title: A METHOD OF ASSESSING AND MANAGING RISKS ASSOCIATED WITH A

PHARMACEUTICAL PRODUCT

AMENDMENT AND RESPONSE TO OFFICE ACTION UNDER 37 C.F.R. § 1.111

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This Amendment and Response constitutes a complete and timely reply to the Office Action mailed June 25, 2009 in the above-identified application. The following remarks are respectfully submitted.

Amendments to the Claims begin on page 2.

Remarks begin on page 14.